IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: DJURUP2

In re Application of:
Rene DJURUP et al.

IA No: PCT/DK04/00634

IA Filed: September 17, 2004

Appln. No.: 10/572,603

For: PRO-INFLAMMATORY AND ANTI-INFLAMMATORY ANTIBODIES...

Atty. Docket: DJURUP2

Conf. No.: 2533

Art Unit:

Examiner:

Washington, D.C.

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents U.S. Patent and Trademark Office Customer Service Window Randolph Building, Mail Stop Amendment 401 Dulany Street Alexandria, VA 22314

Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §\$1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

- [X] 1. This IDS should be considered, in accordance with $37\ \text{CFR}\ \$1.97$, as it is filed:
- [] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- [XX]B. before the mailing date of a first office action on the merits or before the mailing of a first Office

action after the filing of a Request for Continued Examination under 37 CFR §1.114; or

- [] C. after (A) and (B) above, but before final rejection or allowance, and Applicant has made the necessary certification (box "i" below) or paid the necessary fee (box "i" below):
 - [] i. Counsel certifies that, upon information and belief, each item of information listed herein either was
 - [] (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
 - [] (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, not known to any individual designated in 37 CFR \$1.56(c) more than three months prior to the filing of this IDS.
 - [] ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in 37 CFR \$1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035 of the undersigned.
- [] D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant states as follows under 37 CFR \$1.97(e) for consideration of this IDS, that, upon information and belief, each item of information listed herein either was
 - [] (a) first cited in a communication from a foreign patent office in a counterpart foreign

application not more than three months prior to the filing of this IDS; or

[] (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in 37 CFR \$1.56(c) more than three months prior to the filing of this IDS.

Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in 37 CFR \$1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035 of the undersigned.

- [X] 2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form BN/SB/08A/B) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. Other than U.S. patent(s) and/or published U.S. application(s), which 37 CFR §1.98(a)(2)(ii) does not require to be filed unless specifically required by the Office, a copy of each document listed is attached, except as explained below:
- [] A. Document(s) ______ is/are deemed substantially cumulative to document(s) ______, and, in accordance with 37 CFR \$1.98(c), a copy of each of the former document(s) is not enclosed.
- [] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

(insert serial numbers and filing dates of prior applications)
Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449, PTO/SB/08a and/or PTO/SB/08b (or their BN form equivalents) from the files of the prior application(s) or a fresh BN/SB/08A and/or BN/SB/08B listing these documents, and request that they be considered and made

3

of record in accordance with 37 CFR \$1.98(d). Per 37 CFR \$1.98(d), copies of these documents need not be filed in this application.

- [X] 3. Document \underline{AI} is not in the English language. In accordance with 37 CFR $\S1.98(a)(3)$, Applicant states:
 - [X] An English translation of each document AI (or of the pertinent portions thereof), or a copy of an English-language abstract (or claim) is enclosed.
 - [] For documents ______, a corresponding English-language patent or published application is included on the accompanying Form BN/SB/08A, with a line drawn in the margin connecting the non-English-language document with its corresponding English-language document.
 - [] A concise explanation of the relevance of document(s) _____ is found in the attached _____ search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).
 - [] A concise explanation of the relevance of document(s) _____ is set forth as follows:
 - [] A concise explanation of the relevance of
 document(s) _____ can be found on page(s)
 of the specification.
 - [] A concise explanation of the relevance of document(s) ____ can be found on the attached sheet.
- [X] 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).
- [] 5. Other information being provided for the examiner's consideration follows:

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK Attorneys for Applicant(s)

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SHEET 1 OF 5

SUBSTITUTE FOR FORM IPC/SB/08 INFORMATION DISCLOSURE STATEMENT LIST OF DOCUMENTS CITED BY APPLICANT			ATTY DOCKET NO: DJURUP2 SERIAL NO: 10/572,603				
			FIRST INVENTOR: Rene DJURUP, et al. FILING DATE: March 20, 2006				
			U.S. PATE	NT DOC	CUMENTS (include at le	ast patentee, patent/p	ub number and filing/issue
EXAM. INITIAL	ID	DOCUMENT NUMBER	FILING, ISSUE OR PUBLICATION DATE MM-DD-YYYY	PATENTEE OR APPLICANT	Relevant Passage(s)	Т,	
	AA	US 4,036,945	July 19, 1977	Haber			
	АВ	US 4,331,647	May 25, 1982	Goldenberg	1		
	AC	US 4,599,311	July 8, 1986	Kawasaki			
	AD	US 4,683,202	July 28, 1987	Mullis			
-	AE	US 4,816,567	March 28, 1989	Cabilly, et al.			
	AF	US 4,946,778	August 7, 1990	Ladner, et al.			
	AG	US 5,458,874	October 17, 1995	Pereira, et al.			
	AH	US 5,484,885	January 16, 1996	Pereira, et al.			
FOREIGN	PATEN	T DOCUMENTS (include	at least document n	umber, publication date and	country)		
EXAM. INITIAL	ID	COUNTRY CODE & DOCUMENT NUMBER	PUBLICATION DATE MM-DD-YYYY	PATENTEE OR APPLICATION	Relevant Passage(s)	T [*]	
	Al	EP 404,097	December 27, 1990	Behringwerke			
	AJ	WO 89/08666	September 21,1989	Nordisk Gentofte A/S			
	AK	WO 91/00907	January 24, 1991	Emory University			
	AL	WO 93/11161	June 10, 1993	Enzon, Inc.			
EXAMINER				DATE CONSIDERED			

^{* &}quot;Relevant Passages" column is optional. Put check in "T" column if English translation of entire document included. If English language abstract included, put A in this box. If ref. in English, put "E". If requirement otherwise met, put O.

SHEET 2 OF 5

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OTHER DOCUMENTS (include AUTHOR, title, name of publication, volume, pages & date of publication) Please list in alphabetical order.					publication) Please
AM Alber, T. et al "Nucleoti cerevisiae"; Jour. of Mol			de Sequence of the Triose Phosphate Isomerase Gene of Saccharomyces ecular and Applied Genetics, 1982, 1:419-434.		
	AN	Beaucage, S. L. et al. "Deoxynucleoside Phosphoramidites-A New Class of Key Intermediates for Deoxypolynucleotide Synthesis"; 1981, Tetrahedron Lett. 22:1859-1862.			
	AO	Bird, R.E., et al. "Single-Chain Antigen-Binding Proteins" Science, October 21, 1988, Vol. 242, 423-426.			
	AP	Chertov, O, et al. "Identification of Defensin-1, Defensin-2, and CAP37/Azurocidin as T-cell Chemoattractant Proteins Released from Interleukin-8-stimulated Neutrophils"; February 9,1996, J. Biol. Chem. 271:2935-2940			
	AQ	Chothia, C. "Domain Association in Immunoglobulin Molecules- The packing of variable domains"; J. Mol. Biol. 1985, 186, 651-663.			
	AR	Corsaro, C.M. et al., "Enhancing the Efficiency of DNA-Mediated Gene Transfer in Mammalian Cells"; 1981, Somatic Cell Genetics, Vol. 7, No. 5, p. 603-616.			
•	AS	Flodgaard, H., et al. "Covalent structure of two novel neutrophile leucocyte-derived proteins of porcine and human orgin"; 1991, Eur. J. Biochem. 197: 535-547.			
	АТ				s" ; July 1989, Proc.
	AU	Gautam, N., et al. "Kinetics of leukocyte-induced changes in endothelial barrier function"; 1998 Br. J. Pharmacol.;125(5):1109-1114.			
	AV	Graham, F.L et al., "A new technique for the assay of infectivity of Human Adenovirus 5 DNA"; 1973, Virol. 52:456-467.			
	AW	Hitzeman, R.A., et al. "Isolation and Characterization of the Yeast 3-Phosphoglycerokinase Gene (PGK) by an Immunological Screening Technique"; 1980, J. Biol. Chem. 255:12073-12080			
	AX	Holliger, P., et al. "Diabodies": Small bivalent and bispecific antibody fragments; Proc. Natl. Acad. Sci. USA, Vol. 90, pp. 6444-6448, July 1993.			
	AY	Holmes, M.A., et al. "Structural Consequences of Humanizing an Antibody"; The Journal of Immunology, 1997, 158: 2192-2201			
	AZ	Jones, P.T., et al. "Replacing the complementarity-determining regions in a human antibody with those from a mouse" Nature, Vol. 321, 29 May 1986.			
EXAMINER				DATE CONSIDERED	
EXAMINER: Initial if reference considered. Draw line through citation if not in conformance and not considered. Include					

copy of this form with next communication to applicant.

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SHEET 3 OF 5

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OTHER DO	CUME abetica	NTS (include AUTHOR, ti	itle, name of publication, volume, pages & date of	publication) Please	
BA Kaufman, R.J. et al, "Am			plification and Expression of Sequences Cotransfected with a Modular Complementary DNA Gene"; J. Mol. Biol. 159, 1982, pp. 601-621		
	вв	Keire, D.A., et al. "Diethyl Phthalate, a Chemotactic Factor Secreted by <i>Helicobacter pylori</i> "; J. Biol Chem. December 2001, 276: 48847-48853.			
	вс	Linde, V., et al. "Measurement of Apoptosis by the TUNEL Method Using Scintillating Microplates" ; Anal. Biochem. 2000, 280:186-188			
	BD	Loyter, A, et al., "Mechanisms of DNA uptake by mammalian cells: Fate of exogenously added DNA monitored by the use of fluorescent dyes"; January 1982, Proc. Natl. Acad. Sci. USA 79: 422-426			
	BE	Marks, J.D., et al. "By-passing Immunization Human Antibodies from V-gene Libraries Displayed on Phage" J. Mol. Biol. 1991, 222, 581-597.			
	BF	Matthes, H.W.D., et al. "Simultaneous rapid chemical synthesis of over one hundred oligonucleotides on a microscale"; 1984, EMBO J. 3:801-805.			
	BG	McKnight, G.L., et al. "Identification and molecular analysis of a third Aspergillus nidulans alcohol dehydrogenase gene"; 1985, EMBO J. 4:2093-2099			
	вн	Mercer-Jones, M., et al. "Monocyte recruitment increases survival in fecal peritonitis"; 1996, Surgical Forum, pp. 106-108.			
	ВІ	Morrison, S.L., et al. "Chimeric human antibody molecules: Mouse antigen-binding domains with human constant region domains"; Proc. Natl. Acad. Sci. USA, Vol. 81, pp. 6851-6855, November 1984.			
	BJ	Neumann, E., et al. "Gene transfer into mouse lyoma cells by electroporation in high electric fields" 1982, EMBO J. 1:7:841-845.			
	вк	Novotny, J., et al. "Structural invariants of antigen binding: Comparison of immunoglobulin V _L -V _H and V _L -V _L domain dimmers"; Proc. Natl. Acad. Sci. USA, Vol. 82, pp.4592-4596, July 1985.			
	BL	Ostergaard, E., et al. "A neutrophil-derived proteolytic inactive elastase homologue (hHBP) mediates reversible contraction of fibroblasts and endothelial cell monolayers and stimulates monocyte survival and thrombospondin secretion" ;April 1992, J. Leuk. Biol. 51:316-323.			
	ВМ	Pack, P., et al. "Improved Bivalent Miniantibodies, with Identical Avidity as Whole Antibodies, Produced by High Cell Density Fermentation of <i>Escherichia coli</i> "; Bio/Technology, Vol. 11, November 1993, pp 1271-1277			
EXAMINER	1		DATE CONSIDERED		

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OTHER DO	CUME	NTS (include AUTHOR, ti	tle, name of publicat	on, volume, pages & date of	publication) Please	
list in alphabetical order. Palmiter, R.D., et al. "Me Science 222: 809-814			allothionein-Human GH Fusion Genes Stimulate Growth of Mice";1983,			
	во	Pereira, H.A., et al. "Synthetic bactericidal peptide based on CAP37: A 37-kDa human neutrophil granule-associated cationic antimicrobial protein chemotactic for monocytes"; May 1993, Proc. Natl. Acad. Sci. USA 90: pp. 4733-4737				
	ВР	Pereira, H.A., et al. "CAP37, a Human Neutrophil-derived Chemotactic Factor with Monocyte Specific Activity"; May 1990, J. Clin. Invest. 85:1468-1476				
	BQ	Pohl, J., et al. "Amino acid sequence of CAP37, a human neutrophil granule-derived antibacterial and monocyte-specific chemotactic glycoprotein structurally similar to neutrophil elastase"; October 1990, FEBS Lett. 272: 1,2, pp. 200-204.				
	BR	Presta, L.G. "Antibody engineering"; Current Opinion in Structural Biology, 1992, Vol. 2, pp.593-596.				
	BS	Rasmussen, P.B., et al. "Characterization of recombinant human HBP/CAP37/azurocidin, a pleiotropic mediator of inflammation-enhancing LPS-induced cytokine release from monocytes"; 1996, FEBS Lett. 390:109-112				
	вт	Riechmann, L., et al. "Reshaping human antibodies for therapy" ;Nature, Vol. 332, 24 March 1988, pp. 323-329.				
	BU	Russell, D.W., et al. "DNA sequences of two yeast promoter-up mutants" August 1983, Nature 304:652-654				
	BV	Saiki, R.K., et al. "Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase" January 29, 1988, Reports, pp. 487-491.				
	BW	Shafer, W.M., et al. "Late Intraphagosomal Hydrogen Ion Concentration Favors the In Vitro Antimicrobial Capacity of a 37-Kilodalton Cationic Granule Protein of Human Neutrophil Granulocytes"; Infect. Immun. September 1986, 53:3:651-655				
	вх	Southern, PJ., et al. "Transformation of Mammalian Cells to Antibiotic Resistance with a Bacterial Gene Under Control of the SV40 Early Region Promoter"; 1982, J. Mol. Appl. Genet. 1:327-341				
	BY	Subramani, S., et al. "Expression of the Mouse Dihydrofolate Reductase Complementary Deoxyribonucleic Acid in Simian Virus 40 Vectors"; September 1981, Mol. Cell Biol. 1:9:854-864				
	BZ	Young, T., et al. "The alcohol dehydrogenase genes of the yeast, Saccharomyces Cerevisiae: Isolation, Structure and Regulation";1982, in Genetic Engineering of Microorganisms for Chemicals., pp. 335-361				
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Vasudevan, S., et al. "M CA infected Sf9 insect cells 1992, FEBS Lett. 311:1:			uscarinic acetylcholine receptor produced in recombinant baculovirus couples with endogenous G-proteins to activate ion channels"; October 7-11			
	СВ	Vaswani, S.K., et al. "Humanized antibodies as potential therapeutic drugs"; Annals of Allergy, Asthm Immunology, Vol. 81, August 1998, pp. 105-115.				
	СС	http://firstsearch.oclc.org; "4th International Congress on the Immune Consequences of Trauma, Shock and Sepsis, Munich- Mechanisms and Therapeutic Approaches"; FirstSearch: WorldCat Detailed record; Germany, 1997				
	CD	Wigler, M., et al. "Biochemical Transfer of Single-Copy Eucaryotic Genes Using Total Cellular DNA as Donor"; Cell, July 1978, 14:725-731.				
	CE	Wilde, C.G., et al. "Characterization of Two Azurophil Granule Proteases with Active-site Homology to Neutrophil Elastase"; February 5, 1990, J. Biol. Chem, 265:4:2038-2041				
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